

US EPA ARCHIVE DOCUMENT



**U.S. Environmental Protection Agency
Office of Pesticide Programs**

PESTICIDE LABELING CONSISTENCY –
“FOR USE ONLY BY” ISSUE PAPER
OPP SYNOPSIS AND DISCUSSION OF COMMENTS RECEIVED

October 24, 2006

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I. Background

In early 2006, the Office of Pesticide Programs (OPP) Labeling Committee invited comment on a short issue paper concerning the use of label statements such as “for professional use only”, “for commercial use only” and the like, on products not classified for restricted use. All discussion in this paper relates to products that do not meet the toxicity criteria for Restricted Use classification (40 CFR 152.170 (b) or (c)).

EPA and state pesticide regulators generally agree that these terms are not enforceable against sellers and questionable against users, because they have no definitions in law or regulation. Consequently, they are not likely to be effective as limitations on users. EPA’s Label Review Manual (LRM) states that overly general, undefined terms are not appropriate, however, over time many such statements have found their way onto approved labels.

The purpose of this paper is to provide feedback to the states, registrants and organizations who commented on the 2006 issue paper. This paper includes a synopsis of the main points raised by regulators and industry groups; provides clarification of EPA positions on some of these issues; and discusses possible next steps for addressing these issues.

II. Synopsis of Comments

Below is EPA’s summary of the principal points made by the state regulators and by pesticide registrants, and pesticide applicators in their comments. These are EPA’s interpretive summaries, and do not capture many details or differences among the individual comments received.

Main Points Made by State Regulatory Agencies

14 individual states and 1 association of state officials commented.

* Most expressed the opinion that “for professional/commercial use only” statements are wholly unenforceable. A few states do try or have tried in the past to impose state restrictions when such language was encountered, but with varying degrees of success.

* Most states felt that the statements are misleading, can cause confusion to users, the public and sometimes enforcement personnel.

- * Such statements were felt to undermine the authority of label language that really is meant to be enforced, since these “prohibitions” are phrased as mandatory but are not enforceable.
- * The state agencies feel that if a user limitation is meant to accomplish risk mitigation, it needs to be clearly enforceable. However, they feel “professional/commercial use only” statements are often used only as a marketing tool by registrants and not for risk mitigation, and that there is no obligation to enforce such statements.

Main Points by Industry

4 individual registrants and 3 trade associations commented.

- * Industry has a right to market products to specific segments of the user community.
- * Some labels are aimed at professionals for practical reasons – e.g., complex directions, or equipment requirements unrealistic for the general public.
- * Several commenters felt the regulators have too narrow a view of what is enforceable (see “Clarification” discussion below).
- * Some commenters were willing to support labels more likely to be enforceable, such as limiting to state licensed applicators.
- * 8 individual pest control operators (PCOs) and their trade association want to limit sales as well as users, similar to Restricted Use Products (RUPs).

III. Clarification of EPA Positions

1. Enforceable use/user limitations.

In general, EPA believes that clearly identifiable uses and groups of users can be designated on labels, and the limitation of product use (but not necessarily sale) can be enforced. Some categories of users are defined in the FIFRA statute itself or its implementing regulations. For example, “certified applicator” and its two subsets, “commercial applicator” and “private applicator” are defined in both statute (FIFRA sec. 2(e)), and regulations (40 CFR 171.2(a)(8), (9) and (20)). However, these definitions are tied to the use of restricted use pesticides. EPA believes that attempting to limit use of a non-RUP to certified applicators, as some commenters have suggested, would confuse the distinction with restricted use classification, and could lead to products being misbranded. The statute also defines “maintenance applicator” and “service technician” (FIFRA section (2) (jj) and (kk) respectively), but to date, registrants have not elected to limit use to these categories.

Some commenters stated the belief that EPA has taken a position that user limitations can only be enforced for RUPs. This is not the case. EPA has limited certain non-RUPs to

specific user groups, and believes these limitations are enforceable when the designated user group can be clearly identified, even though they are not specifically defined in statute or regulation. In practice, this usually means the user can produce some form of government license or credential. Current examples include a state license to perform termiticide treatments (for soil applied termiticides); a veterinarian license (for various products); or evidence of employment or supervision by a health or vector control agency authorized to conduct mosquito control (for wide-area ULV adulticides). In general, EPA believes that such clearly identifiable groups of users can be designated on labels, and the limitation of product use to that group can be enforced.

Rather than identifying users of a product, it should be noted that designating the allowable use sites on the label is generally the more effective and enforceable tool for controlling use. Thus, the terms “institutional use” and “residential use”, which are defined in 40 CFR 152.3, can be employed for risk mitigation and also have the effect of steering a product toward or away from being marketed to the general public.

2. Regulating sales of RUP versus non-RUP products.

FIFRA section 12(a)(2)(F) makes it unlawful to sell or distribute RUPs except in accordance with EPA regulations, but there is no comparable provision for the sale of products not classified for restricted use (assuming they are properly registered, not misbranded, not adulterated, etc.). Some commenters thought that FIFRA section 12(a)(2)(G) making it unlawful “to use any registered pesticide in a manner inconsistent with its labeling,” provides authority to restrict the sale of products to persons designated on the label, even if the product is not classified as restricted use. However, this interpretation would require the Agency to construe a “sale” of a pesticide as a type of “use.” The Agency does not appear to have previously taken such a position, and it is not clear that such a position could be maintained.

3. Marketing versus risk mitigation.

EPA agrees that pesticide registrants have some discretion in targeting products toward different segments of the market. As a general principle, however, EPA agrees with the state commenters that if limiting use is necessary in order to mitigate a risk concern that might otherwise be an obstacle to registration, then the label language needs to be enforceable in some manner. The Agency also recognizes that a user limitation that is primarily intended to target a product to a particular market may also have collateral risk mitigation benefits, such as keeping the product away from inexperienced users more likely to misuse it. However, if the limiting language offers only incidental mitigation benefits and is not considered a term or condition of registration meant to address an identified risk, then the Agency would prefer registrants to use other means to achieve their marketing goals, and not to propose labels with undefined terms that have the appearance of mandatory statements.

IV. Conclusions

1. The use of pesticide products can be enforceably limited to specific groups of applicators provided they are clearly identifiable. Clearly identifiable persons include applicators defined in statute or regulation, or who can be identified by a license or other government issued credential, or who can demonstrate employment by an entity identified on the label, such as a vector control agency. However, it is not appropriate to include on the label of a non-restricted use product any language limiting use to certified applicators.

2. Use and user limitations required by the Agency as terms or conditions of registration in order to mitigate risk must be stated in enforceable, mandatory terms.

3. Advisory language -- such as "recommended (or not) for XXX use" -- is acceptable for marketing purposes, but is not enforceable and creates no obligations on sellers or enforcement agencies.

4. For non-restricted use products, specifying allowable or prohibited use sites, including but not limited to "institutional use" and "residential use" (both defined in regulations) is generally preferable to limiting user groups.

V. Next Steps

At this time, the OPP Labeling Committee is not planning regulatory action to address these issues, in part because another part of OPP is planning rulemaking that may have a substantial effect in this area. Under the auspices of the Pesticide Program Dialogue Committee (PPDC), a Worker Safety Regulatory Enhancement workgroup is considering substantial revisions to both the worker safety regulations (40 CFR Part 170) and the certification and training regulations (Part 171). The changes being considered for Part 171 would result in expanding the universe of occupational pesticide users that would be required to demonstrate competency in some form. If the Agency finalizes a rule to accomplish this, there would be many more commercial/professional pesticide users clearly identified in a manner similar to certified applicators, and who therefore could be designated on labels in an enforceable manner.

Since Part 171 revisions would be a formal rulemaking, it could take several years to achieve. Accordingly, the OPP Labeling Committee is considering as an interim measure revising the Label Review Manual (LRM) to give more detailed guidance to label reviewers on this issue. The current LRM guidance is very brief and would benefit from a more thorough explanation of this issue with more examples provided. The Committee is also interested in continuing dialogue with industry on the subject of how they can reasonably achieve their marketing goals without using misleading and inappropriate language.